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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,202

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Randall J. Huebner

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

06/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/712,202	<b>Applicant(s)</b> HUEBNER ET AL.	
	<b>Examiner</b> JERRY CUMBERLEDGE	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-9, 11, 13-15, 17-26, 28 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-9, 11, 13-15, 17-26, 28 and 31-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-9, 11, 13-15, 17-26, 28 and 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lahille et al. (US Pat. 5,743,912) in view of McTighe et al. (US Pat. 5,653,765).

Lahille et al. disclose a method of compressing a bone, comprising: selecting a bone screw (Fig. 8, ref. 30) including a shank (Fig. 8, ref. 31) including a thread disposed externally for threaded engagement with bone (Fig. 8, ref. 30), the shank defining a long axis and a direction of advancement into bone (Fig. 8), and a head (Fig. 8, ref. 45) connected to the shank. The step of selecting a bone screw includes a step of selecting a bone screw in which the shank has a proximal portion adjacent the head and a distal portion spaced from the head, and wherein the thread is restricted to the distal portion (Fig. 8). The step of selecting a bone screw includes a step of selecting a bone screw that is self-tapping (Fig. 8). The step of selecting a bone screw includes a step of selecting a bone screw in which the shank includes a tip region configured to cut a hole in the bone as the bone screw is advanced into the bone (Fig. 8). The step of selecting a bone screw includes a step of selecting a bone screw in which the plurality of

shoulders ledge structures have a corresponding plurality of diameters, and wherein the diameters decrease successively toward the shank. The step of selecting a bone screw includes a step of selecting a bone screw in which the head is shaped generally as a frustum of a cone (Fig. 8). The step of selecting a bone screw includes a step of selecting a bone screw in which the shank and the head define opposing ends of the bone screw and further define an axial bore extending between the opposing ends (Fig. 1, ref. 101). The step of selecting a bone screw includes a step of selecting a bone screw in which the axial bore includes a widened region configured to receive a tool that engages the head (Fig. 1, ref. 122). The step of selecting a bone screw includes a step of selecting a bone screw in which the head is rotatably and/or slidably connected to the shank (Fig. 8)(Fig. 7).

Lahille et al. disclose a method of compressing a bone, comprising: selecting a bone screw (Fig.8) including a shank including a proximal region (Fig. 8), a distal region (Fig. 8), and a thread (Fig. 8, ref. 30) disposed externally for threaded engagement with bone and restricted to the distal region (Fig. 8), and a head (Fig. 8, ref. 45) connected to the shank and spaced from the thread by the proximal region (Fig. 8). The step of selecting a bone screw includes a step of selecting a bone screw in which the head is generally frustoconical in shape (Fig. 8). The step of selecting a bone screw includes a step of selecting a bone screw in which the shank defines a long axis, wherein the head has a maximum diameter, wherein the head has an axial length that is measured parallel to the long axis, wherein the head has an aspect ratio defined by the axial length of the head relative to the maximum diameter of the head, and wherein the

aspect ratio is at least 1:1 (Fig. 8). At least one shoulder slopes radially outward generally toward the direction of advancement into bone (Fig. 8).

Lahille et al. disclose a method of compressing a bone with a bone screw, comprising: forming a hole in the bone (Fig. 8); selecting a bone screw (Fig. 8) having a shank (Fig. 8, ref. 31) and a head (Fig. 8, ref. 45) connected to the shank (Fig. 8). The step of forming a hole includes a step of forming a bore and a counterbore (Fig. 3), and wherein the step of advancing disposes the head and the shank at least substantially in the counterbore and the bore, respectively (Fig. 3)(Fig. 8). The step of forming a hole is performed by the step of advancing (Fig. 8). The portion of the bone near the head and the portion of the bone near the shank are separated by a fracture in the bone (Fig. 8). Each shoulder slopes radially outward, generally toward the direction of advancement into bone (Fig. 8).

Lahille et al. disclose a method of compressing a bone, comprising: selecting a bone screw (Fig.8) including a shank (Fig. 8, ref. 31) including a thread (Fig. 8, ref. 30) disposed externally for threaded engagement with bone, the shank defining a long axis and a direction of advancement into bone (Fig. 8), and a head connected to the shank (Fig. 8, ref. 45).

Lahille et al. do not disclose a plurality of shoulders disposed at spaced positions generally along the head, each shoulder ledge structure facing generally toward the direction of advancement and extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis; and installing the bone screw in a bone such that a portion of the bone near the head is engaged by two or

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more of the shoulders ledge structures and is urged toward a portion of the bone near the shank. The step of selecting a bone screw includes a step of selecting a bone screw in which the shoulders are formed by a plurality of ridges, a plurality of grooves, or both. The step of selecting a bone screw includes a step of selecting a bone screw in which one or more of the plurality of shoulders ledge structures extend in a closed loop corresponding to a circle. The step of selecting a bone screw includes a step of selecting a bone screw in which the head includes a plurality of steps defined by stepwise decreases in the diameter of the head, and wherein the plurality of shoulders ledge structures are included in the plurality of steps. Lahille et al. do disclose a threaded portion on the head (column 9, lines 33-38) that is used to apply a compressive force to bone (column 11, lines 26-67)(column 12, lines 1-5).

McTighe et al. disclose a device used in orthopedic surgery (abstract) that comprises a portion (Fig. 1, near ref. 34) which comprises a plurality of shoulders that extend around the device (Fig. 1, ref. 34), the shoulders being used to provide rotary stability, to stimulate bone growth, and to cause compression (column 4, lines 46-62).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted a threaded portion on the head as taught by Lahille et al. with shoulders as taught by McTighe et al. in order to achieve the predictable result of compression. Furthermore, the device of Lahille et al. would gain the additional benefits of rotational stability and stimulation of bone growth (column 4, lines 46-62).

With regard to the elements that require "installing the bone screw as a unit", it is noted that the device of Lahille et al. is installed as a unit as in Fig. 9, since the components are all within the bone.

Lahille et al. in view of McTighe et al. disclose the claimed invention except for the shank and the head being both part of the same monolithic structure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the shank and the head of Lahille et al. in view of McTighe et al. as part of the same monolithic structure, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

### ***Response to Arguments***

Applicant's arguments filed 03/04/2008 have been fully considered but they are not persuasive.

With regard to Applicant's argument that the device of Lahille et al. in view of McTighe et al. would be rendered unsatisfactory for its purpose if the device was modified in such a way as explained by the examiner, the examiner respectfully disagrees. Initially, both the threads on the head (column 9, lines 33-38)(column 11, lines 26-67)(column 12, lines 1-5) disclosed by Lahille and the shoulders (Fig. 1, ref. 34) (column 4, lines 46-62) disclosed by McTighe et al. are used for compressive purposes. Since both the thread and the ledges are being used for the same purpose it would have been obvious to a person to have substituted one for the other to achieve a predictable result of applying compressive force to bone.

Secondly, the examiner disagrees that modifying the device of Lahille et al. with shoulders rather than threads would make the device of Lahille et al. unsatisfactory for its intended function as the Applicant suggests. The examiner asserts that replacing the threads of the head of Lahille et al. with the shoulders of McTighe would not destroy the functioning of the device, but would rather only change the mechanism that is being used to apply the compression.

With regard to Applicant's argument that the substitution must replace only a part of threaded anchor portion 11 with the shoulders of McTighe, the examiner notes that the entirety of the head portion of Lahille et al. can be replaced with the shoulders as taught by McTighe.

With regard to Applicant's argument that the elliptical shape of the McTighe et al. reference would be problematic as the device is used, the examiner notes that the McTighe reference teaches a device used in orthopedic surgery (abstract) that comprises a portion (Fig. 1, near ref. 34) which comprises a plurality of shoulders that extend around the device (Fig. 1, ref. 34), the shoulders being used to provide rotary stability, to stimulate bone growth, and to cause compression (column 4, lines 46-62). The examiner further notes that the test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art. If one uses shoulders as taught by McTighe et al. in place of the threads as taught by Lahille et al. one of ordinary skill in the art would recognize that the shoulders would need to be conformed to the outer circumference of the Lahille et al.



device in order for the device to operate. Furthermore, one of ordinary skill would recognize that the shape of the underlying structure of the McTighe et al. device (*i.e.* the body of the device) is formed to a specific part of the body, and that the shoulders are placed onto the underlying body structure in order to conform to the underlying body structure.

With regard to the claim elements that require "installing the bone screw as a unit", it is noted that the device of Lahille et al. is installed as a unit as in Fig. 9, since the components are all within the bone when the surgical procedure is completed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is

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(571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733